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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,593	10/25/2001	Douglas A. Collins	COP1008US	6800

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KING & SPALDING LLP
191 PEACHTREE STREET, N.E.
ATLANTA, GA 30303-1763

EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,593	COLLINS ET AL.	
	Examiner	Art Unit	
	Traviss C McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 in part, drawn to compound of formula I wherein X is H, cyano, halogen, haloalkyl, NO, NO_2, NO_3, phosphonates, $PR^{15}R^{16}R^{17}$, NH_2, $NR^{15}R^{16}$, OH, OR^{15}, SR^{15}, SCN, N_3, $OC(O)R^{15}$, $C(O)_2R^{15}$, $OC(O)NR^{15}R^{16}$, $C(O)_2NR^{15}R^{16}$, $C(O)NR^{15}R^{16}$, $P(O)_2OR^{15}$, $S(O)_2R^{15}$, alkyl, alkenyl, alkynyl, aryl, aralkyl, alkaryl, heteroalkyl, heterocycle, heteroaryl, or alkylheteroaryl, and T is a therapeutic agent classified in class 536, subclass 26.4.

II. Claims 1-11 in part, drawn to compound of formula I wherein X is H, cyano, halogen, haloalkyl, NO, NO_2, NO_3, phosphonates, $PR^{15}R^{16}R^{17}$, NH_2, $NR^{15}R^{16}$, OH, OR^{15}, SR^{15}, SCN, N_3, $OC(O)R^{15}$, $C(O)_2R^{15}$, $OC(O)NR^{15}R^{16}$, $C(O)_2NR^{15}R^{16}$, $C(O)NR^{15}R^{16}$, $P(O)_2OR^{15}$, $S(O)_2R^{15}$, alkyl, alkenyl, alkynyl, aryl, aralkyl, alkaryl, heteroalkyl, heterocycle, heteroaryl, or alkylheteroaryl, and T is a diagnostic agent classified in class 424, subclass 1.73.

III. Claims 1-11 in part, drawn to compounds of formula I wherein X is a purine or pyrimidine nucleoside, a nucleoside analog, adenosyl, 5-FU, or a carbohydrate, and T is a therapeutic agent classified in class 536, subclass 26.4.

IV. Claims 1-11 in part, drawn to compounds of formula I wherein X is a purine or pyrimidine nucleoside, a nucleoside analog, adenosyl, 5-FU, or a carbohydrate, and T is a diagnostic agent classified in class 424, subclass 1.73.

V. Claims 1-11 in part, drawn to compounds of formula I wherein X is an amino acid, and T is a therapeutic agent classified in class 536, subclass 26.4.

VI. Claims 1-11 in part, drawn to compounds of formula I wherein X is an amino acid, and T is a diagnostic agent classified in class 424, subclass 1.73.

VII. Claims 1-11 in part, drawn to compounds of formula I wherein X is a peptide and T is a therapeutic agent, classified in class 536, subclass 26.4.

VIII. Claims 1-11 in part, drawn to compounds of formula I wherein X is a peptide and T is a diagnostic agent, classified in class 424, subclass 1.73.

IX. Claims 1-11 in part, drawn to compounds of formula I wherein X is a protein and T is a therapeutic agent, classified in class 536, subclass 26.4.

X. Claims 1-11 in part, drawn to compounds of formula I wherein X is a protein and T is a diagnostic agent, classified in class 424, subclass 1.73.

XI. Claims 12-14 in part, drawn to compositions comprising the compound of Group I, classified in class 514, subclass 52.

XII. Claims 12-14 in part, drawn to compositions comprising the compounds of Group II, classified in class 424, subclass 1.73

XIII. Claims 12-14 in part, drawn to compositions comprising the compounds of Group III, classified in class 514, subclass 52.

XIV. Claims 12-14 in part, drawn to compositions comprising the compounds of Group IV, classified in class 424, subclass 1.73

XV. Claims 12-14 in part, drawn to compositions comprising the compounds of Group V, classified in class 514, subclass 52.

XVI. Claims 12-14 in part, drawn to compositions comprising the compounds of Group VI, classified in class 424, subclass 1.73.

XVII. Claims 12-14 in part, drawn to compositions comprising the compounds of Group VII, classified in class 514, subclass 52.

XVIII. Claims 12-14 in part, drawn to compositions comprising the compounds of Group VIII, classified in class 424, subclass 1.73.

XIX. Claims 12-14 in part, drawn to compositions comprising the compounds of Group IX, classified in class 514, subclass 52.

XX. Claims 12-14 in part, drawn to compositions comprising the compounds of Group X, classified in class 424, subclass 1.73.

XXI. Claims 15-28 in part, drawn to methods of treating a proliferative disorder other than neoplasms comprising administering the compound or composition of Group I to a patient, classified in class 514, subclass 52.

XXII. Claims 15-28 in part, drawn to methods of treating a neoplastic proliferative disorder comprising administering the compound or composition of Group I to a patient, classified in class 514, subclass 52.

XXIII. Claims 15-28 in part, drawn to methods of diagnosing a proliferative disorder other than neoplasms comprising administering the compound or composition of Group II to a patient, classified in class 424, subclass 9.1+.

XXIV. Claims 15-28 in part, drawn to methods of diagnosing a neoplastic proliferative disorder comprising administering the compound or composition of Group II to a patient, classified in class 424, subclass 9.1+.

XXV. Claims 15-28 in part, drawn to methods of treating a proliferative disorder other than neoplasms comprising administering the compound or composition of Group III to a patient, classified in class 514, subclass 52.

XXVI. Claims 15-28 in part, drawn to methods of treating a neoplastic proliferative disorder comprising administering the compound or composition of Group III to a patient, classified in class 514, subclass 52.

XXVII. Claims 15-28 in part, drawn to methods of diagnosing a proliferative disorder other than neoplasms comprising administering the compound or composition of Group IV to a patient, classified in class 424, subclass 9.1+.

XXVIII. Claims 15-28 in part, drawn to methods of diagnosing a neoplastic proliferative disorder comprising administering the compound or composition of Group IV to a patient, classified in class 424, subclass 9.1+.

XXIV. Claims 15-28 in part, drawn to methods of treating a proliferative disorder other than neoplasms comprising administering the compound or composition of Group V to a patient, classified in class 514, subclass 52.

XXX. Claims 15-28 in part, drawn to methods of treating a neoplastic proliferative disorder comprising administering the compound or composition of Group V to a patient, classified in class 514, subclass 52.

XXXI. Claims 15-28 in part, drawn to methods of diagnosing a proliferative disorder other than neoplasms comprising administering the compound or composition of Group VI to a patient, classified in class 424, subclass 9.1+.

XXXII. Claims 15-28 in part, drawn to methods of diagnosing a neoplastic proliferative disorder comprising administering the compound or composition of Group VI to a patient, classified in class 424, subclass 9.1+.

XXXIII. Claims 15-28 in part, drawn to methods of treating a proliferative disorder other than neoplasms comprising administering the compound or composition of Group VII to a patient, classified in class 514, subclass 52.

XXXIV. Claims 15-28 in part, drawn to methods of treating a neoplastic proliferative disorder comprising administering the compound or composition of Group VII to a patient, classified in class 514, subclass 52.

XXXV. Claims 15-28 in part, drawn to methods of diagnosing a proliferative disorder other than neoplasms comprising administering the compound or composition of Group VIII to a patient, classified in class 424, subclass 9.1+.

XXXVI. Claims 15-28 in part, drawn to methods of diagnosing a neoplastic proliferative disorder comprising administering the compound or composition of Group VIII to a patient, classified in class 424, subclass 9.1+.

XXXVII. Claims 15-28 in part, drawn to methods of treating a proliferative disorder other than neoplasms comprising administering the compound or composition of Group IX to a patient, classified in class 514, subclass 52.

XXXVIII. Claims 15-28 in part, drawn to methods of treating a neoplastic proliferative disorder comprising administering the compound or composition of Group IX to a patient, classified in class 514, subclass 52.

XXXIX. Claims 15-28 in part, drawn to methods of diagnosing a proliferative disorder other than neoplasms comprising administering the compound or composition of Group X to a patient, classified in class 424, subclass 9.1+.

XXXX. Claims 15-28 in part, drawn to methods of diagnosing a neoplastic proliferative disorder comprising administering the compound or composition of Group X to a patient, classified in class 424, subclass 9.1+.

The inventions are distinct, each from the other because of the following reasons:

Groups I-X are independent and distinct from each other as they are drawn to compounds which have divergent moieties in the X position and either a therapeutic or diagnostic agent in the T position. Each of groups I-X is directed to or involves the use of compounds which have X-groups that are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects, and reactive conditions. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e., they are patentable over each other. Chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the

structure of the claimed invention. Note that in accordance with the holding of ***Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)***, and ***In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984)***, chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure. It is noted that the therapeutic agents in the T position of groups I, III, V, VII and IX have a different function than the diagnostic agents in the T position of Groups II, IV, VI, VIII, and X. Moreover, the moieties of the various groups in the X position would not be expected to have similar functions, as such, the Groups I-X are seen to be independent and distinct from each other.

It is noted that if applicant elects a compound from groups I-X, the composition correlative to said elected group will be examined together with the compound. That is, if applicant elects the compound of Group I, they are entitled to the search of the composition of Group XI-XX comprising the same.

Inventions I and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of using the product of Group I can be practiced in the method of Group XXII.

Likewise, the method of using the product of group III can be practiced in either the method of group XXV or XXVI; the method of using the product of group V can be practiced in the method of group XIX or XXX; the method of using the product of group VII can be practiced in the method of group XXXIII or XXXIV; and the method of using the product of group IX can be practiced in the method of group XXXVII or XXXVIII.

Inventions II and XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of using the product of Group II can be practiced in the method of Group XXIV.

Likewise, the method of using the product of group IV can be practiced in either the method of group XXVII or XXVIII; the method of using the product of group VI can be practiced in the method of group XXXI or XXXII; the method of using the product of group VIII can be practiced in the method of group XXXV or XXXVI; and the method of using the product of group X can be practiced in the method of group XXXIV or XXXX.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper. It would indeed impose an undue burden upon the examiner in charge of this application if the instant restriction requirement is not set forth.

Claims 1-28 are generic to a plurality of disclosed patentably distinct species comprising a plethora of divergent compounds represented by the Markush group of formula I. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By a single species it is meant a single compound. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the Markush group represents, or 4) by naming a claim or an example which itself sets forth a single compound.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
June 25, 2004

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623